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DRUG PRICE COMPETITION AND PATENT TERM RESTORATION ACT: THE ELIMINATION OF COMPETITION BETWEEN DRUG MANUFACTURERS

Jaclyn L. Miller^{*}

INTRODUCTION

The pharmaceutical industry has become a focal point in the last two decades due to the concern over rising drug prices. Today, brand name prescription drug prices are monitored closely by the health care industry as well as the government. Congress recently has attempted to pass legislation concerning the rising prices of drugs. However, the last successful enactment of legislation that affects the prices of drugs was the Drug Price Competition and Patent Term Restoration Act. This legislation was meant to address the issue of rising drug prices by enacting various statutes meant to control the practices of brand name manufacturers and enable generic manufacturers to participate more actively in the market.¹ Throughout our recent history of trying to make drugs more accessible to all, brand name pharmaceutical manufacturers have become the scapegoat of the situation. They have been portrayed as the “bad guys” who block the entry of generic

^{*}Editor in Chief, DePaul Journal of Health Care Law. B.A., Purdue University, 1999; J.D. (Cand.), DePaul University College of Law, 2002. This article is dedicated to Dustin Davis whose ideas, love and support are inspirational to me, and to my parents, Alan and Dawn Miller who have blessed my life infinitely with their love, support, and encouragement.

¹Justina A. Molzon, *The Generic Drug Approval Process*, 5 J. PHARMACY & LAW 275, 276 (1996) (discussing the steps generic drugs go through to be approved by the FDA and highlighting the passage of the Drug Price Competition and Patent Term Restoration Act).

manufacturers into the market, and are thus out to gouge Americans by overcharging for drugs.²

Drugs are a vital part of our society today. They not only increase people's quality of life, but they save lives. These two benefits of pharmaceutical drugs are what make high prices so hard for people to handle. People struggle when forced to put a price on life or the quality of one's life. While costly drugs are an enormous problem this nation must address, blaming one side—brand name manufacturers—is not a sound solution. Although, brand name manufacturers are the ones who design the product and ultimately choose the price of prescription drugs, the problem of rising drug prices is not simply a large company out to get any company that gets in the way; it is not that cut and dry. The problem is far more complex than the explanation the media, the generic manufacturers and the public hears from Congress. The solution does not come down to simply lowering the prices, or an unwillingness to do so by brand name manufacturers. Rather, the problem is due to a multiple of factors, which converge together and prevent “true competition” thus lowering prices. This comment will focus on the current view of the pharmaceutical industry, the multiple factors involved in the drug pricing problem, and how these factors come together to create the current problem. In the first section of the article, the background of the pharmaceutical industry will be reviewed and the legislation will be explained.³ The second part of this comment will analyze pharmaceutical legislation and illustrate how the laws have helped create the current problem of rising drug prices.⁴

BACKGROUND

Pharmaceutical Industry

Before health care was revolutionized into the present system of managed care the pharmaceutical industry and prescription prices were barely a concern.⁵ Insurance companies did not reimburse patients for

²Melissa K. Davis, *Monopolistic Tendencies of Brand name Drug Companies in the Pharmaceutical Industry*, 15 J.L. & COM. 357 (1995).

³See *infra* pp. 92-101.

⁴See *infra* pp. 101-107.

⁵Kevin J. Dunne & Ciara R. Ryan, *How Management of Medical Costs is Revolutionizing the Drug Industry*, 62 DEF. COUNS. J. 177 (1995).

prescription drugs and did not look at the cost of prescriptions.⁶ Physicians were also not concerned with drug prices since they were separate entities, (i.e.—not associated with a Managed Care Organization) and simply prescribed whatever drug they thought best regardless of price.⁷ Physicians rarely turned to lower cost alternatives because they were free to prescribe a more costly original.⁸ Pharmacists were also prevented from asking patients if they preferred to substitute the original prescribed drug, as they often do now, because of ant substitution laws.⁹ Therefore, before managed care the health care industry did not focus on the cost of prescription pharmaceuticals and, brand name manufacturers had a majority of the market share.¹⁰

Generics were a second thought, if they were thought of at all, and did not play a huge role in the pharmaceutical market.¹¹ However, as the managed care system took hold of the health care industry, prices in every area began to be examined.¹² Managed care's goal is to provide health care in a cheaper and more efficient manner by containing costs at their current level or decreasing them.¹³ Congress, in looking for ways to reduce health care costs, began to focus on the pharmaceutical industry.¹⁴ In focusing on the pharmaceutical industry, many legislators felt lower prices for pharmaceutical drugs could be obtained by increasing competition between generic manufacturers and brand name manufacturers.¹⁵ Immediately, Congress began working with brand name manufacturers and generic manufacturers to come up with legislation that would protect both sides.¹⁶ Congressional legislation

⁶See Dunne, *supra* note 5, at 177.

⁷David A. Balto, *A Whole New World? Pharmaceutical Responses to the Managed Care Revolution*, 52 FOOD & DRUG L. J. 83, 83 (1997).

⁸*Id.* at 83.

⁹*Id.*

¹⁰See Davis, *supra* note 2, at 358.

¹¹*Id.*

¹²See Dunne, *supra* note 5.

¹³*Id.*

¹⁴Amy Stark, Comment, *The Exemption from Patent Infringement and Declaratory Judgments: Misinterpretation of Legislative Intent?*, 31 SAN. DIEGO L. REV. 1057 (1994).

¹⁵Alfred B. Engelberg, *Special Patent Provisions for Pharmaceuticals: Have They Outlived their Usefulness?* 39 J.L. & TECH. 389, 398 (1999). The process involved in passing this legislation was quite in depth. *Id.* It took a couple of years for Congress to reach an agreement with generic and brand name manufacturers. *Id.* After the work that was put into the Act, it was deemed a huge success when it passed Congress. *Id.*

¹⁶*Id.*

that was suppose to provide this compromise was the Price Competition and Patent Term Restoration Act of 1984.¹⁷

Legislative Background

One of the factors contributing to the current problem of rising drug prices is the regulation of the pharmaceutical drug industry. The two main areas of regulation for prescription drugs are patents and the Federal Food, Drug, and Cosmetic Act.¹⁸ These two areas of regulations are closely connected and are further intertwined by the Drug Price Competition and Patent Term Restoration Act.¹⁹ This section explains the relationship that patents and the Federal Food, Drug and Cosmetic Act have to the pharmaceutical industry. This section will also explain how the Drug Price Competition and Patent Restoration Act changed the role patents and the Federal Food, Drug, and Cosmetic Act have in regards to brand name and generic manufacturers.

Patents

The United States Constitution provides Congress with the authority to provide inventors with patents.²⁰ Patents enable the inventor to exclude others from using the invention while the patent is still active.²¹ Infringement of a patent occurs when another party ignores this exclusion and either manufactures, uses, or sells the patented invention while the patent is active.²² Patents are meant to promote innovation by giving innovators a safe period of time to develop their idea and bring it to market before others can capitalize on it.²³ Patents are granted under the theory that disclosure to the public of an invention will provide a great incentive to create other useful inventions.²⁴ Patents are also

¹⁷ Engelberg, *supra* note 15, at 398.

¹⁸ Ronald L. Desrosiers, *The Drug Patent Term: Longtime Battleground in the Control of Health Care*, 24 NEW ENG. L. REV. 115 (1989).

¹⁹ *Id.*

²⁰ U. S. CONST. art. I, § 8, cl. 8.

²¹ Thomas F. Poche, Note, *The Clinical Trial Exemption from Patent Infringement: Judicial Interpretation of Section 271(e)(1)*, 74 B.U.L. REV. 903, 905 (1994) (explaining how patents reward inventors and encourages the development of additional inventions).

²² *Id.*

²³ Thomas T. Gordon & Arthur S. Cookfair, PATENT FUNDAMENTALS FOR SCIENTISTS AND ENGINEERS 9 (1995).

²⁴ *Id.* at 9.

controversial to some because they prevent competition for the life of the patent.²⁵ The need to protect and encourage innovation however, is thought to outweigh the need for competition, making patents an integral part of the world's economy.²⁶

The innovation and marketing of new drugs is extremely dependent on the time provided by patents.²⁷ The manufacturer's main time in which to recoup its investment is during the time of the patent.²⁸ Patents ensure companies that their investment into drug development and research is wise given they provide the inventor with an exclusive time in the market without competition in order to recoup the money they invested while also making a profit.²⁹ If a company does not have a patent on their product, the likelihood of the company recouping its investment.³⁰ Other inventors would be able to market the product on their own, thus lowering the original inventor's market share.³¹ This, in turn, lowers the amount the original manufacturer receives from selling the product.³² If patents did not exist, there would be little invention because the risk of investing millions of dollars only to suffer a financial loss would be too great.³³

In 1861, the life of a patent became seventeen years.³⁴ Prior to the twentieth century, the pharmaceutical manufacturers were able to use the entire seventeen years to market its product.³⁵ This is also the same amount of time other industries receive for their investments. In 1938, the pharmaceutical industry was changed by a new regulation that limited the industry from profiting from the full seventeen years of

²⁵See Stark, *supra* note 14, at 1060 (explaining that this right was given as a "reward...to bring forth new knowledge" (quoting *Graham v. John Deere Co.*, 383 U.S. 1(1966)).

²⁶See Gordon, *supra* note 23.

²⁷John F. Niblack, *Why are Drug Development Programs Growing in Size and Cost? A View From the Industry*, 52 FOOD & DRUG L.J. 151, 153 (1997)("Sales of a patented drug product by the original sponsor-innovator, who incurred all of the research and development costs for the product, can all by fifty-to-eighty percent in the first year following patent expiration...").

²⁸See Poche, *supra* note 21, at 908.

²⁹*Id.* at 907.

³⁰*Id.*

³¹*Id.*

³²See Desrosiers, *supra* note 18, at 124-25.

³³*Id.*

³⁴*Id.* at 118.

³⁵*Id.* at 117.

patent life.³⁶ This regulation, the Federal Food, Drug, and Cosmetic Act, requires manufacturers to prove a drug is safe for humans to ingest before the drug is approved for sale.³⁷ While this regulation is beneficial for the consumer, the requirements cut into the patent period.³⁸ This regulation leaves brand name manufacturers with less time to recoup their initial expenditure of a new drug.³⁹ This issue is addressed by the enactment of the Drug Price Competition and Patent Restoration Act, which provides for a patent extension.⁴⁰ However, the issue of losing time on a patent is still a problem since most companies are either not granted extension or not provided the full extension allotment provided by the Act.⁴¹

Federal Food, Drug, and Cosmetic Act

The Food and Drug Administration, as discussed above, plays a huge role in regulating the pharmaceutical industry. The Federal Food, Drug, and Cosmetic Act effects drug prices by requiring the manufacturers to go through several stages to gain FDA approval for a drug.⁴² Since patents are obtained before manufacturers go through this process, the FDA regulation causes time to be lost on the patent.⁴³ This translates into a direct loss of money for manufacturers.⁴⁴ Before manufacturers even seek FDA approval, they must first go through pre-clinical discovery.⁴⁵ This is the process by which scientists either discover a compound or experiment with a new one.⁴⁶ Once pre-clinical discovery occurs, scientists test the chemical on animals as a "possible pharmacological 'new chemical entity', [to show] that [the

³⁶ See Desrosiers, *supra* note 18, at 118-19.

³⁷ *Id.* at 119.

³⁸ See Stark, *supra* note 14, at 1060 (explaining how patents are obtained after the initial discovery of the product; moreover, the patent is running during the time of development and the time needed to obtain FDA approval).

³⁹ *Id.* at 1057.

⁴⁰ *Id.* at 1060.

⁴¹ See Desrosiers, *supra* note 18, at 140-143.

⁴² 1 JAMES O'REILLY, FOOD AND DRUG ADMINISTRATION, § 13.11, 13-63 (2d ed. 1993).

⁴³ See Poche, *supra* note 21, at 912.

⁴⁴ *Id.*

⁴⁵ See O'REILLY, *supra* note 42, at 13-65.

⁴⁶ *Id.*

chemical] might intercept and combat a disease.”⁴⁷ This step prepares the drug for human testing and lasts an average of 18 months.⁴⁸

The first step to gaining FDA approval begins with the manufacturer submitting an investigational new drug (IND) application.⁴⁹ The application is the method by which the FDA examines the proposed human testing of the drug.⁵⁰ The next step is Phase I of clinical testing.⁵¹ In this phase, different dosages of the drug are given to twenty to sixty “ill patients whose disease is the target of the particular new chemical.”⁵² The purpose of the phase is to gain evidence of effectiveness.⁵³

In phase II, the clinical testing is performed and monitored using “several hundred patients for the clinical effectiveness of the drug.”⁵⁴ These two phases take approximately two years to complete with only one third of the drugs successfully completing these phases.⁵⁵ Phase III is the clinical testing of the drug.⁵⁶ This phase involves thousands of patients and determines the dosage at which the drug is the most effective.⁵⁷ Phase III testing lasts 1-4 years and is the most important phase to the FDA and manufacturers since it determines the overall effectiveness of the drug.⁵⁸ Approximately one fourth of the chemicals survive this phase of testing.⁵⁹

The next stage is the new drug approval stage (NDA).⁶⁰ It begins with meetings between the FDA and manufacturers to discuss IND evidence.⁶¹ Once these meetings are conducted and suggestions of improvement are submitted, the manufacturer prepares the NDA application.⁶² Reviews are again conducted, this time by several

⁴⁷ See O'REILLY, *supra* note 42, at 13-65.

⁴⁸ *Id.*

⁴⁹ *Id.*

⁵⁰ *Id.* at 13-63.

⁵¹ *Id.*

⁵² See Desrosiers, *supra* note 18 at 120; See also O'Reilly, *supra* note 42, at 13-64, 13-65.

⁵³ Desrosiers, *supra* note 18, at 120.

⁵⁴ *Id.*

⁵⁵ See O'REILLY, *supra* note 42, at 13-65.

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ See O'REILLY, *supra* note 42, at 13-65.

⁶¹ *Id.*

⁶² 21 CFR §§314.102, 312.82.

groups, which advise the manufacturer on areas that need improvement.⁶³ After the reviews, the "FDA Drugs Center endorses the recommendation" and a letter of approval is mailed.⁶⁴ Before labeling and packaging is decided, the drug is finally approved and able to be marketed.⁶⁵

The process discussed above is approximately seven years long and requires manufacturers to constantly working with the FDA in an attempt to secure approval for the drug.⁶⁶ When success finally comes, manufacturers on average have spent \$400-500 million and lost seven years off their patents.⁶⁷ That leaves manufacturers still to incur the cost of post approval testing for the FDA as well as marketing, with only 10 years in which to recoup their expenditures.⁶⁸ Most manufacturers contend that it takes 12-19 years to truly recoup the costs of the drugs they make.⁶⁹

Drug Price Competition and Patent Restoration Act

The Drug Price Competition and Patent Restoration Act of 1984 (Hatch-Waxman Act) was thought to be the answer to the rising drug prices and was deemed to be a compromise between the two competing players in the pharmaceutical market—generic manufacturers and brand name manufacturers.⁷⁰ The Act incorporates a benefit for each side.⁷¹ The brand name manufacturers were benefited by the Act's

⁶³O'REILLY, *supra* note 42, at 13-67.

⁶⁴*Id.* at 13-69.

⁶⁵*Id.*

⁶⁶Patent Term Extension and Pharmaceutical Innovation: Hearing before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, 97th Cong., 2d Sess. 18 (1982) (statement of Robert S. Walker, U.S. Representative, Pennsylvania (citing *Where the Patent Laws Don't Work*, Chicago Tribune, May 1, 1981, at 12; *Extending Patents*, San Francisco Chronicle, June 17, 1981, at 13.)).

⁶⁷See Niblack, *supra* note 27, at 151.

⁶⁸O'REILLY, *supra* note 42.

⁶⁹Desrosiers, *supra* note 18, at 124-25.

⁷⁰James J. Wheaton, *Generic Competition and Pharmaceutical Innovation: The Drug Price Competition and Patent Term Restoration Act of 1984*, 35 CATH. U. L. REV. 433, 434-36 (1986).

⁷¹See Stark, *supra* note 14, at 1060 ("The PTR Act was the result of a compromise between two competing economic groups: the generic drug industry and the pioneer drug industry. These groups each lobbied Congress for the passage of legislation to eliminate the patent distortion most harmful to their respective industries.").

patent restoration provision.⁷² The generic manufacturers were benefited by the Act's streamlining of the regulation approval process and allowing immediate competition in the marketplace upon patent expiration by allowing an exemption from infringement activities relating to FDA submissions for generic drugs.⁷³ The Hatch-Waxman Act attempted to balance the public interest of faster access to cheaper generic drugs against the research industry's financial incentive to discover a new drug product.⁷⁴

The section of the Act meant to benefit the brand name manufacturers was patent restoration.⁷⁵ The patent restoration section was meant to enable brand name manufacturers with a means to make up for lost time on their patents due to the regulatory process of getting FDA approval.⁷⁶ The time allotment that a patent gives the brand name drug begins running long before the FDA approves a drug for the market.⁷⁷ Actually, approximately seven years are lost off the patent due to the regulatory process of the FDA.⁷⁸ "Innovators state that they need approximately twelve to nineteen years to gain back the cost of research and development of the drug."⁷⁹ The patent extension section of the Hatch-Waxman Act was designed to put this time back on the patent for the manufacturers, because many were having a hard time recouping the money they expended in making the drug.⁸⁰ The patent extension section was thought to be the solution to this problem.⁸¹

The term of a patent eligible for extension "shall be extended by the time equal to the regulatory review period for the approved product, which period occurs after the date the patent is issued."⁸² Except that

⁷²Wheaton, *supra* note 70, at 435.

⁷³Ned Milenkovich, *Deleting the Bolar Amendment to the Hatch-Waxman Act: Harmonizing Pharmaceutical Patent Protection in a Global Village*, 32 J. MARSHALL L. REV. 751, 755 (1999).

⁷⁴Engelberg, *supra* note 15, at 389.

⁷⁵35 U.S.C.S. § 156 (2000).

⁷⁶Poche, *supra* note 21, at 914.

⁷⁷*Id.* at 913.

⁷⁸*Id.*

⁷⁹Desrosiers, *supra* note 18, at 124-25.

⁸⁰*Id.*

⁸¹See Stark, *supra* note 14, at 1060. Generic and brand name manufacturers came to a compromise and the Hatch-Waxman Act was passed. *Id.* This was believed to be the answer to previous problems faced by both sides. *Id.*

⁸²35 U.S.C.S. § 156(c) (2000).

"each period of regulatory review shall be reduced by any period determined, which the applicant for the patent extension did not act with due diligence during such period of the regulatory review period."⁸³ The difficulty with this provision of the Act is that patent extensions are rarely given.⁸⁴ Patents are hardly ever extended and if patents are extended, the manufacturers are not provided with the total amount of extension time allowed for by the Act.⁸⁵ In 1998, the Patent and Trademark Office (PTO) received ninety applications that were based on human drug products; out of the extensions granted, only two were given the entire period of extension.⁸⁶

Patent extensions were refused for various reasons.⁸⁷ Some refusals were based on the PTO's interpretation of the statute's legislative history that implied that Congress only wanted extensions given to those drugs that had FDA approval for the first time.⁸⁸ Other refusals were based on the fact that the drug's commercial marketing or use was not the initial use or marketing of the product.⁸⁹ It is clear that brand name manufacturers still suffer from the problem of having their patent run out before the manufacturer can recoup its expenditures, since brand name manufacturers are not given the full benefit of the patent extensions that they were supposed to be provided through the Hatch-Waxman Act.⁹⁰ This process has forced many companies out of the research and development part of the pharmaceutical field.⁹¹

The other sections of the Hatch-Waxman Act are meant to benefit generic manufacturers by facilitating competition between generic and brand name manufacturers.⁹² One section assists in facilitating competition by eliminating requirements of the FDA approval process for generic drugs.⁹³ The amendment to the Federal Food, Drug, and

⁸³35 U.S.C.S. § 156(c)(1) (2000).

⁸⁴Desrosiers, *supra* note 18, at 140-43.

⁸⁵*Id.*

⁸⁶*Id.*

⁸⁷*Id.*

⁸⁸*Id.*

⁸⁹Desrosiers, *supra* note 18, at 140-43.

⁹⁰*Id.* at 141-43.

⁹¹*Id.*

⁹²Molzon, *supra* note 1, at 276.

⁹³*Id.*

Cosmetic Act is the Abbreviated New Drug Applications (ANDA).⁹⁴ ANDA provides that so long as the active ingredient in a generic drug is the same as a previously approved drug, the shortened approval process can be followed.⁹⁵ This process allows generics to gain approval without having to duplicate costly research and submit test data to the FDA for purposes of drug approval.⁹⁶ Generic drugs only have to show that the route of administration, dosage form, and strength of the new drug are the same as an already approved brand name drug; the new drug is bioequivalent to the brand name drug, and the labeling proposed for the new drug is the same as the labeling approved for the brand name drug.⁹⁷

The second section of the Hatch-Waxman Act that benefits generic manufacturers is the clinical trial exemption found in 35 U.S.C. § 271(e)(1).⁹⁸ This allows exclusion from the scope of the patent, thus exempting the generic manufacturers from patent infringement when using the brand name product before the patent runs out to conduct their own research for their drug.⁹⁹ This exemption allows generic drug manufacturers to use the inventor's drug product before the patent expires, allowing them to create the generic drug for dramatically less money.¹⁰⁰ In addition to the generic manufacturers benefiting from the reduction in cost, generic manufacturers also benefit from judicial interpretation, which interprets the provision extremely broadly.¹⁰¹ The legislative history of the act suggests that Congress did not intend for this broad interpretation, however, Congress failed to state this directly and thus courts are broadly construing the statute.¹⁰² Courts are basing

⁹⁴Abbreviated New Drug Applications Act, Pub. L. No. 98-417, §101, 98 Stat. 1585 (1996).

⁹⁵*Id.*

⁹⁶Molzon, *supra* note 1, at 276 ("It was recognized that the safety and effectiveness of the drug had been amply demonstrated by adequate and well controlled studies by the pioneer drug manufacturer, by the acceptance of these findings by the medical community, and by the widespread use of these drug entities in patient therapy over many years.").

⁹⁷§101, 98 Stat. 1585.

⁹⁸35 U.S.C. § 271(e)(1) (1995).

⁹⁹*Id.*

¹⁰⁰Molzon, *supra* note 1, at 277-78.

¹⁰¹Courtenay C. Brinckerhoff, *Can the Safe Harbor of 35 U.S.C. § 271(e)(1) Shelter Pioneer Drug Manufacturers?*, 53 FOOD DRUG L. J. 643, 643 (1998). Legislative history of this act shows that the statute was supposed to be much narrower. *Id.* However, the language of the statute is quite broad, and the judicial system has increased this broadness. *Id.*

¹⁰²*Id.*

the broad interpretation of the statute on the wording "reasonably related to the development".¹⁰³ Hence, while courts are perfectly within their bounds to make such liberal interpretations of this phrase, this interpretation severely hurts brand name manufacturers.¹⁰⁴

These two provisions of the Hatch-Waxman Act enable generic manufacturers to produce their product at a highly reduced cost compared to the brand name manufacturers.¹⁰⁵ While the lower costing generic drug translates into less expenditure for HMOs and the public, the thought that these lower costing drugs will increase competition and lower brand name drug prices has backfired.¹⁰⁶ The reason prices are not lowering for brand name drugs stems from the Hatch-Waxman Act and its interaction with patents and the FDA. The following section will analyze the legislation and explain why the legislation and the government's view of the industry are flawed.

ANALYSIS OF CURRENT MODEL

The current view of the pharmaceutical industry focuses on the concept of competition between generic and brand name manufacturers.¹⁰⁷ In most areas the idea of increased competition creating lower prices is a sound conclusion in the economic world. However, in the pharmaceutical industry, this has not materialized—prices are still rising.¹⁰⁸ The different legislation discussed above might create competition that results in two sides against each other, but it does not create "true competition" that results in lowered prices. It is obvious the government and public want true competition but unfortunately, the legislation as is, will never achieve this goal.

There are two reasons why the current view and legislation is flawed and thus fails to create true competition. First, the provisions of

¹⁰³Brinckerhoff, *supra* note 101 at 643.

¹⁰⁴*Id.*

¹⁰⁵35 U.S.C. § 271 (e)(1); §101, 98 Stat. 1585.

¹⁰⁶*See* Desrosiers, *supra* note 18, at 143.

¹⁰⁷*See* Stark, *supra* note 14, at 1057. The Drug Price Competition and Patent Term Restoration Act of 1984 was a measure used to create more competition between generic and brand name manufacturers. *Id.* From the point of the Act being passed, Congress and the public have held the belief that the problem with drug prices rising is a lack of competition between the two sides. *Id.*

¹⁰⁸*See* Desrosiers, *supra* note 18, at 143.

the Hatch-Waxman Act cause unequal benefits between generic and brand name manufacturers. Second, these unequal benefits result in brand name manufacturers having to raise prices not lower them.

Unequal Benefits Between Generic and Brand Name Manufacturers

True competition does not exist between brand name and generic manufacturers because of unequal benefits that the Hatch-Waxman Act bestows on the two sides.¹⁰⁹ These benefits create an unequal playing field that inhibits true competition.¹¹⁰ This section will explain the differences between generic manufacturing and brand name manufacturing of drugs by the Hatch-Waxman Act, and will discuss how these differences are the flaws that prohibit true competition from occurring.

Development and Research Costs

The first difference between brand name and generic drug manufacturing that creates an uneven playing field is the fact that brand name manufacturers have a much higher cost of research and development than generic manufacturers.¹¹¹ Brand name manufacturers spend from \$400-500 million on the drugs that survive the approval process and are marketed for consumers.¹¹² However, there are still far more drugs that brand name manufacturers pour money into which never make it through the FDA approval process.¹¹³ Drug manufacturers have stated that "every year scientists screen more than 126,000 chemicals for potential drug development. Of that number, they will actually follow up on about 1,000. Of that number only sixteen will ever make it through the regulatory process and eventually appear in the pharmacy. Only one tenth of one percent of all chemicals entering the process will finally be approved."¹¹⁴ This means manufacturers spend millions of dollars on research and development on compounds that most likely will never make a profit

¹⁰⁹See 35 U.S.C. §271(e)(1); §101, 98 Stat. 1585; 35 U.S.C.A. §156.

¹¹⁰*Id.*

¹¹¹See Niblack, *supra* note 27; Desrosiers, *supra* note 18,

¹¹²See Niblack, *supra* note 27, at 151.

¹¹³See Patent Term Extension, *supra* note 66.

¹¹⁴*Id.*

for them. Hence, the drugs that do make it to the pharmacy must reimburse not only the money spent to get it to market, but also the money spent on researching the other possibilities that failed. Generic manufacturers do not face this issue. Instead generics are duplicated from brand name drugs.¹¹⁵ They do not incur the cost of developing new chemicals, and thus do not have to incorporate the cost of into the price of their product. Generic manufacturers must simply come up with a bioequivalent to the brand name drug.¹¹⁶ While this takes some time and research, it pales in comparison to the time, research, and expense brand name manufacturers face.

Cost of Approval

In addition to the difference in development and research of drugs, there is a difference in the regulatory approval process between brand name and generic manufacturers. The FDA process for brand name drugs is longer, costlier, and more in depth than the FDA process generic drugs must go through.¹¹⁷ In the Hatch-Waxman Act, Congress made the process easier for generic drugs by creating the Abbreviated New Drug Application (ANDA).¹¹⁸ This process only requires generic manufacturers to prove their drug is bioequivalent to a brand name drug, and that the "active ingredient, dosage form, strength, and route of administration" of the drug are the same as an already approved brand name drug.¹¹⁹ Finally, the generic manufacturers must show that the labeling proposed is the same as the labeling approved for the brand name drug.¹²⁰ This process may bring drugs, which are cheaper onto the market, but granting this benefit to generic manufacturers does not create true competition. It instead pits brand name manufacturers against a side that is given greater cost and time reduction benefits than

¹¹⁵See Molzon, *supra* note 1, at 275. See also Poche, *supra* note 21, at 913. Generic drugs are able to "complete the FDA testing process 'during the active patent term' without infringing the patent." *Id.* Generic drug manufacturers use the active ingredients from the brand name drugs to create their drug. They only alter the inactive ingredients. *Id.*

¹¹⁶§101, 98 Stat. 1585.

¹¹⁷See 21 CFR §314; §101, 98 Stat. 1585.

¹¹⁸See Poche, *supra* note 21, at 913.

¹¹⁹See Molzon, *supra* note 1, at 277 (explaining generic manufacturers must also follow the FDA guidelines imposed on brand name manufacturers in regards to the "identity, strength, quality and purity" of the drug).

¹²⁰§101, 98 Stat. 1585.

brand name manufacturers. Brand name manufacturers cannot compete with this advantage. Brand name drugs still must go through the same costly process to gain approval, and brand name manufacturers' production costs are not decreasing.¹²¹ Brand name manufacturers cannot logically make a drug cheaper than the generic manufacturers or even just a cheaper drug when generic manufacturers are given such an advantage.

Patent Issues

In addition to the difference caused by the shortened FDA approval process for generic drugs, generic manufacturers are also benefited by the clinical trial exemption granted by the Hatch-Waxman Act.¹²² This allows generic manufacturers to use the brand name product before the patent has run out to conduct research on the generic drug.¹²³ Normally, if a company or person used a product in researching their own product, they would be found guilty of patent infringement.¹²⁴ However, this provision of the Hatch-Waxman Act provides protection for generic manufacturers to use these products and not be found guilty of infringing the patent.¹²⁵ In providing this protection and allowing generic manufacturers to use brand name drugs in their research, the Act provides a huge monetary benefit.¹²⁶ This benefit arises because generic manufacturers can now produce their drug faster and they have less research to do.

¹²¹See Desrosiers, *supra* note 18, at 119-22 ("Drug innovators explain the rise in drug prices with a variety of factors. Foremost is the rapid escalation in research and development costs. In 1962, the approximate cost to develop and bring one new drug to the point of marketing was \$6.5 million. In 1976, the cost jumped to about \$54 million." *Id.* at 126-27. The cost in 1989 was estimated at \$94 million. *Id.*).

¹²²See Stark, *supra* note 14, 1061 (The Hatch-Waxman Act amended the "Patent Code to include section 271(e)(1), which provide[d] that 'it shall not be an act of patent infringement to make, use, or sell a patented invention...solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs.'" *Id.*

¹²³See Poche, *supra* note 21, 914. Generic manufacturers are able to use the brand name drug while developing the bioequivalent generic drug before the patent runs out. *Id.* This used to be considered an infringement of the patent, but the Hatch-Waxman Act now provides the generic manufacturers with this benefit. *Id.*

¹²⁴See Stark, *supra* note 14, at 1061-62.

¹²⁵*Id.*

¹²⁶See Desrosiers, *supra* note 18; Molzon, *supra* note 1.

No other field that involves invention provides competing inventors with such an advantage. The patent system is supposed to protect the patentee and this protection is supposed to increase invention.¹²⁷ The pharmaceutical industry is completely opposite.¹²⁸ While protection and patents are still given to the person who invents a drug or chemical first, the industry gives startling assistance to companies trying to copy the invention.¹²⁹ The reason these types of provisions are not seen in other areas of innovation is because they are adverse to the purpose of patents—protection and incentive to invent.¹³⁰ There is a smaller incentive to invent new drugs because brand name manufacturers are not given the same protection that patents are supposed to give. The Hatch-Waxman Act took this away in an effort to spur competition, yet it greatly deters research and development.

While the Hatch-Waxman Act gave generic manufacturers the benefit of a shorter approval process and a clinical trial exemption, brand name manufacturers were given a patent restoration.¹³¹ This was supposed to make up for the time that brand name manufacturers lost on their patents due to the FDA regulations.¹³² Unfortunately, patent restoration does not provide the benefit it was supposed to give. The purpose behind the provision of the Act was to give back to the brand name manufacturers the length of time of the regulatory review.¹³³ However when the provision was passed it contained four ways in which the final extension time could be limited.¹³⁴ First, time can be taken away if the applicant, during the regulatory process, does not act with due diligence.¹³⁵ Second, the regulatory review period can only include one half of the investigational period.¹³⁶ Third, the patent term, plus the patent extension, can not exceed fourteen years. Finally, only one patent may be extended for the same regulatory review period,

¹²⁷See Poche, *supra* note 21, at 906.

¹²⁸See Desrosiers, *supra* note 18, at 124.

¹²⁹*Id.*

¹³⁰See Poche, *supra* note 21, at 906.

¹³¹See, 35 U.S.C. 271(e)(1); §101, 98 STAT. 1585; 35 U.S.C.A. § 156.

¹³²See Stark, *supra* note 14, at 1060.

¹³³*Id.*

¹³⁴See Desrosiers, *supra* note 18, at 140.

¹³⁵*Id.*

¹³⁶*Id.*

even though one drug involves more than one patent.¹³⁷ These factors create a situation in which applications for patent extension are either denied or not given the full allotted amount provided by the statute.¹³⁸ In February 29, 1988, forty extensions were granted for human drug products.¹³⁹ Out of these forty, the regulatory review period had averaged 8.2 years, yet the extension granted for these forty averaged 1.8 years.¹⁴⁰ From these statistics it is obvious that the relief or benefit the Hatch-Waxman Act promised has not materialized. Brand name manufacturers are still losing enormous time due to regulatory review by the FDA. In addition to this failure to provide brand name manufacturers with patent extensions, judicial review of 35 U.S.C. § 271(e)(1) hurts brand name manufacturers and provides generic manufacturers with a benefit that Congress never imaged.¹⁴¹

Current Legislation Results in Brand Name Manufacturers

Raising Prices and Moving into Other Areas

In comparing the two sides of the pharmaceutical industry and the benefits given by the Hatch-Waxman act, it is clear that the benefits are firmly on the side of the generic manufacturer. This provides the public with a wealth of generic drugs at far cheaper prices than their brand name counterparts, but the situation is never going to cause brand name drug prices to go down. Brand name manufacturers are in a situation in which the manufacturers can not, on their own, reduce costs of manufacturing and development. Actually prices are rising for brand name manufacturers in these areas.¹⁴² The brand name manufacturers are prodded by the government to compete with generic manufacturers, yet the generic manufacturers are given the advantage of a shorter approval process and the use of brand name products to conduct research. These advantages cause the two sides to be unbalanced. This lack of balance between brand name and generic manufacturers results in an uneven playing field; a field that prevents "true competition" from occurring. As a result of the pressure from the government to lower

¹³⁷See Desrosiers, *supra* note 18, at 140.

¹³⁸*Id.* at 141-43.

¹³⁹*Id.*

¹⁴⁰*Id.*

¹⁴¹See Brinckerhoff, *supra* note 101, at 643.

¹⁴²See Niblack, *supra* note 27, at 151.

prices, with no assistance to enable the companies to do so, many brand name manufacturers are leaving the drug innovation area. Those companies who have not left have either added generic manufacturing or formularies to what they do. These actions by the brand name manufacturers have been viewed by many as a manner to further monopolize the industry. Yet, the truth of the matter is these actions are done as a way of survival.

Solution

The solution to the problem of rising drug prices can only be found in realizing that brand name and generic manufacturers must be in true competition for prices to go down. To create true competition, the playing field must be equal between the two sides. This field can be equalized by giving brand name manufacturers the full benefit of the patent extensions, as provided by the Hatch-Waxman Act.¹⁴³ By allowing the extensions the Act was supposed to afford the brand name manufacturers, the manufacturers will now be able to recoup more of their initial expense of development and approval, and thus can pass this savings on to the customers. Congress may have to change the provision to make this possible since the PTO is currently interpreting the provision so narrowly.¹⁴⁴ In addition to providing brand name manufacturers with the necessary patent extensions, the playing field could also be made more equal by having Congress amend 35 U.S.C. § 271 (e)(1) to reflect their original intent that was a narrow meaning.¹⁴⁵ This would curtail the judicial interpretation that is currently continuously expanding the statute's provision, and thus protecting generic manufacturers from being found guilty of patent infringement.¹⁴⁶ This amendment would allow brand name manufacturers to be in an equalized position since they would retain more of the protection their patents are supposed to provide.

These changes give the pharmaceutical companies more equality against the benefits provided the generic manufacturers by the Hatch-Waxman Act. These changes would also enable the brand name manufacturers to provide some relief in regards to rising drug prices. However, this solution can not and will not lower their prices to the

¹⁴³§101, 98 STAT. 1585.

¹⁴⁴See Brinckerhoff, *supra* note 101, at 643.

¹⁴⁵See Brinckerhoff, *supra* note 101.

¹⁴⁶*Id.*

level of generic drugs, since there is no way to eliminate the difference between generic and brand name manufacturers when it comes to approval costs and developmental and research costs. Even if it was possible to dispose of some of the red tape and paper work that brand name manufacturers must go through to get FDA approval, brand name manufacturer will still have more costs involved than generic manufacturers. Also, it is not possible to eliminate the fact that manufacturers' outlays are rising and this cost will be carried over into the cost of drugs seen by the public.

Hence, while the solution of providing the patent extensions to brand name manufacturers and limiting the judicial broadening of 35 U.S.C. § 271 (e)(1) should provide some relief to brand name manufacturers in regards to cost, this cost reduction should be seen in drug prices. While this is not an overall solution to the problem of rising drug prices, it is a positive step in the right direction.

CONCLUSION

Prices for brand name pharmaceuticals will not go down under the method that the government is currently using. Brand name manufacturers can not compete with generic manufacturers to produce lower costing drugs because of the deferential in the initial cost outlay to produce a new drug compared to a generic drug. In addition, current legislation hinders brand name manufacturers while benefiting generic manufacturers. The hindrance placed on brand name manufacturers, in fact, causes them to raise their prices in an effort to stay in research and development.

If America wants new innovative drugs to treat the sick and cure the dying, the current system must change. The government must stop believing that the brand name manufacturers are out to gouge the American people of their money. They must look at the true reasons that drug prices are high. Costs of producing these drugs are constantly escalating. While FDA approval is necessary, it is inefficient and costly. Laws enable generics to enter the market before brand name manufacturers can get their initial costs reimbursed. These factors are what make up the present problem of drug prices. The current problem is not coming from one source; it is caused by many dependent factors, which makes a solution harder to find. However, a solution must be

found that does not discourage brand name manufacturers. One worse fate than high priced pharmaceuticals is no new pharmaceuticals—and this is a very real threat.